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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,726	12/02/1999	DAVID M READ	52951-USA-7A	2987

7590                    03/28/2002

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 03/28/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

ME7

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/453,726	READ, DAVID M
	Examiner MONZER R CHORBAJI	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 January 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

This non-final office action is in response to the amendment received on 01/07/2000

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 5-13, and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (U.S.P.N. 5,955,025) in view of Bealing et al (U.S.P.N. 5,990,199).

With respect to claims 1-3, 5-8, 10-13, 15-18, 21; Barrett teaches the following: hydrogen peroxide sterilization indicator (col.2, lines 28-34), substrate (col.2, line 42), indicator composition including an alkali blue colorant (col.3, table) which changes color in the presence of hydrogen peroxide vapor (col.3, lines 13-18) and a colorant (col.4, table, quinacridone red) which does not change color upon contact with hydrogen peroxide vapor (col.3, lines 60-66), a method of monitoring a hydrogen peroxide

sterilization process by exposing the article along with the indicator to hydrogen peroxide vapor (col.2, lines 57-61 and columns 4-7). However, Barrett fails to specifically disclose specific examples of alkali blue colorants. Bealing et al, which is in the art of using indicators for hydrogen peroxide vapor sterilization processes (col.3, lines 55-67 and col.4, lines 1-18), teaches that various types of the family of alkali blue colorants are used as colorants (col.6, lines 32-38. Please note that alkali blue 6B is acid blue # 119) in the art of vapor sterilization using hydrogen peroxide vapor. Thus, a person skilled in the art would have been motivated to utilize the teachings of Bealing et al to Barrett to provide an indicator including colorants which change color when contacted with hydrogen peroxide vapor and colorants which do not change color when contacted with hydrogen peroxide vapor (Barrett, col.2, lines 27-46).

With respect to claim 22; Barrett teaches that the temperature of the hydrogen peroxide vapor is at about 45 degree Celsius to about 50 degree Celsius (col.4, lines 45-48). Even though, Barrett does not teach a pressure values the low temperature hydrogen peroxide vapor of such a process intrinsically include such pressure values.

With respect to claims 9, and 19-20; Bealing et al discloses the following: the substrate is a polyester film (col.10, line 45), and the binder is shellac (col.3, lines 15-16).

4. Claims 4, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (U.S.P.N. 5,955,025) in view of Bealing et al (U.S.P.N. 5,990,199) and further in view of Patel (U.S.P.N. 5,053,339).

The teachings of Barrett have previously been set forth with regard to claims 1-3, 5-13, and 15-22. With respect to claims 4 and 14; Barrett fails to teach such limitations.

The teachings of Bealing et al have previously been set forth with regard to claims 1-3, 5-13, and 15-22. With respect to claims 4 and 14; Bealing et al fails to teach such limitations. However, Patel teaches the use of hydrogen peroxide vapor as a sterilant (col.11, lines 56-57 an line 60) and those colorants such as brilliant green (col.12, line 37) and others (col.12, lines 25-63) are known to be used in the art of designing indicators (col.1, lines 43-61). Thus, a person skilled in the art would have been motivated to utilize the teachings of Patel and Bealing et al to Barrett in order to be able to choose from the various known types of colorants in the art of designing indicators for hydrogen peroxide vapor sterilization processes.

***Response to Arguments***

5. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Ignacio (U.S.P.N. 6,063,631) teaches the use of two colorants wherein one colorant changes color when contacted with hydrogen peroxide vapor and the other colorant does not. Also, Ignacio teaches the use of alkali blue.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.
8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.
9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*  
Patent Examiner  
AU 1744  
March 20, 2002

*Robert J. Warden, Sr.*  
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